



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,206	08/05/2003	Russell Powers	4002-3357/PC934.00	6826
52196	7590	09/27/2006		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709				
			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
DATE MAILED: 09/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary

Application No.

10/634,206

Applicant(s)

POWERS ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-28,30,31,33-39 and 56-72 is/are pending in the application.
- 4a) Of the above claim(s) 10-16,18,19,21,27,28,30,31,33-39 and 56-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9,17,20 and 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|---|--|

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 7/10/06 is acknowledged. Applicant specifically pointed out that claims 4 and 26 in the restriction requirement belonged in Group I, despite the Examiner showing why these could be different inventions. The Examiner respectfully disagrees, but has grouped these claims with Group I and the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,5-9,17,20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. (5306309). Wagner et al. show (Fig. 5) an elongate spinal implant **50** with a number of bone anchors **70,74** adapted to secure the implant between vertebrae. Wagner discloses the implant is packaged in a kit and sterilized, col. 2, lines 60,61. Wagner also discloses the surgical kit is packaged and contains instrumentation with the spinal implant, col. 2, lines 65-68. Wagner discloses the implant can have bone growth promoting substances thereon for causing fusion between vertebrae, col. 6, lines 37-45. Wagner additionally discloses the instrument is used and designed for planned disposal, col. 4, lines 9,10.

Claims 3,4,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Henniges et al. (2002/107574). Fig. 1 shows a surgical plate **10** and a number of bone

screws **12** to secure the plate. Fig. 11A shows a driver instrument **24** with a shaft or first portion **372** and a second handle portion **15** and an end portion to drive the screws into bone. Henniges et al. disclose the equipment is packaged, paragraph 60. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Clearly, the packaging is "adapted to" integrally contain and maintain the spinal implant and instrumentation in a common container and in sterile condition.

Claims 3-6,8,9,26 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Banick et al. (2003/93153). Fig. 7 shows a surgical kit **60** for use in spinal surgery comprising a spinal implant **20**, instrumentation **52** for use in the surgery, a template or instructions **64** and packaging **66** to contain the kit in a sterilized condition prior to surgery. The implant is fully capable of engagement between first and second vertebrae. Fig. 4 shows the implant is elongate. Banick et al. disclose that a bone growth material can be used in the intervertebral space for fusion, paragraph 40. The instrumentation is fully capable of being used in a single surgery or a limited number of surgeries. Banick also discloses the template or instructions can be provided external to the packaging to maintain sterile conditions for the implant, paragraph 37. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Clearly, the

packaging is "adapted to" integrally contain and maintain the spinal implant and instrumentation in a common container and in sterile condition.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banick et al. (2003/93153) in view of Paikoff et al. (4523679). Banick is explained supra. However, Banick fails to specifically disclose a plurality of compartments to hold the kit components or that there is an inner and outer container to maintain sterility or that the packaging is clear. Paikoff et al. show packaging for medical instrumentation with a plurality of compartments. Paikoff also teaches that the packaging is formed with an inner and outer container, col. 3, lines 55-65, col. 4, lines 38-43. It is also well known that the plastic is clear such that the surgeon can see what is in the package. Paikoff additionally teaches that the different compartments are used to allow for different sterilized products, col. 3, lines 42-45, 65-68. It would have been obvious to one of ordinary skill in the art to use multi compartments as taught by Paikoff to package the spinal kit of Banick so that no damage is done to the different components of the kit while packaged and sterilized under sterilization procedures.

Response to Arguments

Applicant's arguments filed 3/3/06 have been fully considered but they are not persuasive. In response to applicant's argument that the Wagner reference fails to

Art Unit: 3738

show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., instrumentation that degrades) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant also argues that Henniges patent does not disclose "packaging adapted to" integrally contain and maintain the spinal implant and instrumentation in a common container and in sterile condition. However, it should be noted that the claim only requires "packaging" that is clearly disclosed by the prior art references of Henniges and Banick. This argument does not distinguish over the prior disclosing the claimed products because the recitation that "adapted to...." is indefinite, in that it is merely functional language not supported by a recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172: 388 O.G. 279.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

